

B. Remarks

Applicants extend their thanks to the Examiner for his explanation of the rejections. Applicants have responded accordingly and believe the application is in a condition for allowance.

1. 35 USC §112, 1st ¶**a. 35 USC §112, 1st ¶****1. Written description**

The Examiner's contentions appear to be that Applicants are only enabled for a method of treating rheumatoid arthritis by inhibiting the reactivity of lymphocytes associated with rheumatoid arthritis. The Examiner specifically indicates that he is concerned with the use of the words "modulating," "fragments thereof," and "any autoimmune disease." Applicant will address each concern and request reconsideration.

The term "modulating" is defined on page 4 of the specification, second paragraph. The paragraph states that "it has been found that the mere presence of HC gp-39 at a site of inflammation or in lymph nodes draining such a site, for instance as the result of production during the process of monocyte to macrophage maturation, can result in the activation of modulatory T-cells induced with the use of HC gp-39, and therefore result in downmodulation of disease activity." Accordingly, "modulating" is defined and Applicants request reconsideration.

As for "fragments thereof," Applicants amended the claims to incorporate the limitation of, wherein said fragments are selected from one or more of SEQ ID

NO:1(FGRSFTLAS), SEQ ID NO:2(FTLASSETG), SEQ ID NO:3(YDDQESVKS), SEQ ID NO:4(FSKIASNTQ), SEQ ID NO:5(PTFGRSFTLASSE), SEQ ID NO:6(RSFTLASSETGVG), SEQ ID NO:7(VGYDDQESVKSKV), and SEQ ID NO:8(SQRFSKIASNTQSR). Accordingly, Applicants respectfully request reconsideration.

As for "any autoimmune disease," Applicants direct the Examiner to the prior art studies that indicate that HC gp-39 is expressed under immune conditions in which maturation occurs, indicating that potentially in all inflammatory autoimmune diseases HC gp-39 can be found. (Krause S. W. et al, 1996, Journal of Leukoc. Biol., 60, 540). This indicates that while HC gp-39 may not be the direct cause of the inflammation associated disease, it is a result of the localized inflammation. The Examiner has stated that the invention is enabled as to rheumatoid arthritis. Therefore, as the induction of HCgp-39 reactive modulator cells is beneficial for rheumatoid arthritis, for the unwanted immunological activity resulting in expressing HC gp-39, it necessarily follows that it would be beneficial for other diseases in which the immunological activity results in expression of HC gp-39. Accordingly, enablement of the invention has been provided.

2. Written Description

Claims 4-15 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner keys on the fact that the written description of the invention does not provide or enable a

method of treating any inflammatory autoimmune disease by "modulating the reactivity of lymphocytes comprising the effective amount of any fragment thereof of any HP gp-39 and a pharmaceutical acceptable carrier, wherein said lymphocytes are reacted to any antigens other than HC gp-39 which are present in the same tissue as HC gp-39.

Applicants have amended the Claims and respectfully request reconsideration of the rejection.

2. 35 USC §102

Applicants have amended a typographical error. SEQ ID NO 6 was misidentified, by error. The correction has been made. Accordingly, Applicants respectfully request reconsideration of the rejection.

II. Conclusion

Applicants respectfully request reconsideration of the rejections in light of this response and hereby petition for a one month extension of time. The application is believed in a condition for allowance and Applicants respectfully request such action. Applicants respectfully request the examiner contact the undersigned attorney for an interview to expedite prosecution of the case. Please charge deposit account number 02-2334 for any required fees.

Date:

8/20/03

Sincerely,

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